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10/557,515

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EXAMINER

MCEVOY, THOMAS M

ART UNIT

PAPER NUMBER

3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/557,515 | <b>Applicant(s)</b><br>FUKUZAWA ET AL. |  |
|                              | <b>Examiner</b><br>THOMAS MCEVOY     | <b>Art Unit</b><br>3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 11-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on October 2<sup>nd</sup> 2008. Applicant has stated that claim 8 reads on the elected species of Figures 5-8. However, claim 8 recites a 'plate spring' which is included in the non-elected species of Figures 9A and 9B. Accordingly, claim 8 is withdrawn from consideration as being drawn to a non-elected species.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent).

Regarding claims 1-3 and 6, Garthe et al. disclose a lancing device comprising: a first moving member, 40 or 51 or 40/51, holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target

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portion by the lancing member; a second moving member 60 connected to the first moving member, for controlling the movement of the first moving member upon the movement of the second moving member; a housing 11 for accommodating the first and the second moving members, while allowing the movement of the moving members; and an elastically deforming impact absorbing means 152 connected to the housing for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation. Regarding claim 9, the lacing device further comprises a link 61 connecting the first and the second moving members for moving the first moving member upon the movement of the second moving member, wherein the first moving member is formed with a groove for allowing movement of a shaft of the link (Figures 4A-C).

4. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Marshall et al. (WO 01/13794).

Regarding claims 1-3, Marshall et al. disclose a lancing device comprising: a first moving member 20 holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 29 connected to the first moving member, for controlling the movement of the first moving member upon the movement of the second moving member; a housing 44/11 for accommodating the first and the second moving members, while allowing the movement of the moving members; and an elastically deforming rubber impact absorbing means 30 connected to the housing for absorbing impact that is caused when the first and the second moving members come

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to stop on puncture operation (p. 6, lines 13-19; Figure 7). Regarding claims 4 and 5, the housing has a projection 27 which laterally fixes member 29 and thus rubber ring 30 (Figure 7). Regarding claim 6, the elastic member can be a coil spring 22 intervening between the housing and the first moving member (Figure 7). Regarding claim 7, the second moving member 29 can be regarded as an operation portion. It has a portion 32 protruding out of an opening of the housing (Figure 7). The elastic member 30 is provided around (at) the operation portion (Figure 7).

5. Claims 1-3, 6, 9 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitson et al. (US 7,144,404 B2).

Regarding claims 1-3 and 6, Whitson et al. disclose a lancing device comprising: a first moving member 22/24 holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 12 connected to the first moving member, for controlling the movement of the first moving member upon the movement of the second moving member; a housing 240/242 for accommodating the first and the second moving members, while allowing the movement of the moving members; and an elastically deforming impact absorbing means (within 24, Figure 78) connected to the housing for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation (p. 6, lines 13-19; Figure 7). Regarding claim 9, a link 16 connects the first and second moving members and the second moving member 12 has grooves which allow the shaft of the link to rotate and move. Regarding claims 24 and 25, retreat of the second moving member (positions 3 to 1,

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Figure 7) results in advance and retreat of the first moving member. Regarding claim 26, member 20 can be regarded as the second moving member which rotates to advance the first moving member.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent) in view of Alden et al. (US 7,033,371 B2) in view of Stanton (US 2,993,698).

Regarding claim 10, Garthe et al. disclose the device as described above but fail to disclose an elastic support in the groove. Alden et al. teach that mechanical stops in a lancet (such as the groove of Garthe et al.) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Stanton discloses that a vibration transferred to a link in a groove (similar to the link and groove of Garthe et al.) can be minimized by lining the groove with rubber (col. 3, lines 1-11 and elsewhere). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (groove sections) of the Garthe et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the groove to dampen the vibrations as taught by Stanton.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731